



PTO/SB/08a (08-03)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 6

**Complete if Known**

Application Number	10/753,078
Filing Date	January 8, 2004
First Named Inventor	David H. REIFSNYDER
Art Unit	1656
Examiner Name	Schnitzer, Holly G.
Attorney Docket Number	012441.00050 (PP-16331.004)

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/AR/		US- 4,637,834	01-20-1987	Thurrow	
		US- 4,966,852	10-30-1990	Wun et al.	
		US- 5,051,497	09-24-1991	Fanning et al.	
		US- 5,276,015	01-04-1994	Khourl et al.	
		US- 5,358,708	10-25-1994	Patel	
		US- 5,503,827	04-02-1996	Woog et al.	
		US- 5,466,783	11-14-1995	Wun et al.	
		US- 5,563,123	10-08-1996	Innis et al.	
		US- 5,589,359	12-31-1996	Innis et al.	
		US- 5,824,644	10-20-1998	Abendschein	
		US- 5,885,781	01-05-1999	Johnson et al.	
		US- 5,902,582	08-15-1996	Hung	
		US- 6,063,764	05-16-2000	Creasey et al.	
		US- 6,103,500	08-15-2000	Innis et al.	
✓		US- 6,242,414	06-05-2001	Johnson	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
/AR/		EP 0 473 564 A1	03/04/92	Monsanto Co.		
		EP 0 559 632 A2	09/08/93	Monsanto Co.		
		WO 93/25230 A1	12/23/1993	G.D. Searle & Co.		
		WO 93/24143	12/9/1993	Cetus Oncology Corporation		
		WO 96/04378	02/15/1996	Chiron Corporation		
		WO 96/01649	01/25/1996	Washington University		
✓		WO 96/40224	12/19/1996	Chiron Corporation		
		WO 97/09063	03/13/1997	Chiron Corporation		

Examiner  
Signature

/Agnes Rooke/ (09/30/2008)

Date  
Considered

09/30/2008

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Sheet

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Attorney Docket Number

**Complete If Known**

Application Number	10/753,078
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<b>Filing Date</b>	January 8, 2004
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First Named Inventor	David H. REIFSNYDER
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Art Unit	1656
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Examiner Name	Schnizer, Holly G.
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Attorney Docket Number	012441.00050 (PP-16331.004)
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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY			
/AR/		EP 0 414 374 B1	10/08/1997	Smithkline Biologicals S.A.		
		EP 0 755 438 B1	02/14/2001	Amgen Inc.		
		WO 93/18150 A1	09/16/1993	Biocine Sclavo S.P.A.		
		WO 96/01272 A1	01/18/1996	Rican Limited		
		WO 96/01273 A1	01/18/1996	Rican Limited		
		WO 99/57280	11/11/1999	Chiron Corp.		
		WO 01/64922 A2	09/07/2001	Chiron SPA		

Examiner Signature	/Agnes Rooke/ (09/30/2008)	Date Considered	09/30/2008
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Sheet 3 of 6

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Application Number	10/753,078
Filing Date	January 8, 2004
First Named Inventor	David H. REIFSNYDER
Art Unit	1656
Examiner Name	Schnizer, Holly G.
Attorney Docket Number	012441.00050 (PP-16331.004)

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/AR/		Rainer Rudolph, "Successful Protein Folding on an Industrial Scale", Protein Engineering: Principles and Practice, Chapter 10, pps. 283-298 (1996)	
		Rudolph & Little, "In Vitro Folding of Inclusion Body Proteins", Folding of Acidic Fibroblast Growth Factor, FASEB J., 10, pps. 49-50	
/AR/		Dabora et al., "Effect of Polyanions on the Refolding of Human Acidic Fibroblast Growth Factor", The Journal of Biological Chemistry, Vol. 266, No. 35, pps. 23637-23640 (1991)	
/AR/		Bernhard Fisher et al., "Isolation, Renaturation, and Formation of Disulfide Bonds of Eukaryotic Proteins Expressed in Escherichia coli as Inclusion Bodies", Biotechnology and Bioengineering, Vol. 41, pps. 3-13 (1993)	
/AR/		J. Harenberg, et al., "Tissue Factor Pathway Inhibitor: Proposed Heparin Recognition Region, Blood Coagulation and Fibrinolysis, Vol. 6, Supp. No. 1, pps. S50-S56 (1995)	
/AR/		Mark E. Gustafson et al., "Renaturation and Purification of Human Tissue Factor Pathway Inhibitor Expressed in Recombinant E. Coli, Protein Expression and Purification", Vol. 5, pps. 233-241 (1994)	
		Carr, C. et al., "Recombinant E-Coli-Derived Tissue Factor Pathway Inhibitor Reduces Coagulopathic and Lethal Effects in the Baboon Gram-Negative Model of Septic Shock", Wiley-Liss, Div. John Wiley & Sons, Inc., 605 Third Ave., New York, NY 10158-0012	
/AR/		Curless et al., "Phosphate Glass as a Phosphate Source in High Cell Density Escherichia Coli Fermentations", Biotechnology Progress, vol. 12, pp. 22-25 (1996) XP002238061	
/AR/		Malaoui et al., "Influence of Glucose on Glycerol Metabolism by Wild-Type and Mutant Strains of Clostridium Butyricum E5 grown in Chemostat Culture", Applied Microbiology and Biotechnology, vol. 55, December 2000 (2000-12), pp. 226-233, XP002237996	
/AR/		Vagabov et al., "Dependence of Inorganic Polyphosphate Chain Length on the Orthophosphate Content in the Culture Medium of the Yeast Saccharomyces Cerevisiae", Biochemistry (Moscow), vol. 65, 2000, pp. 349-354, XP002237997	

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Sheet

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of

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**Complete if Known**

Application Number	10/753,078
Filing Date	January 8, 2004
First Named Inventor	David H. REIFSNYDER
Art Unit	1656
Examiner Name	Schnizer, Holly G.
Attorney Docket Number	012441.00050 (PP-16331.004)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. †	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ‡
/AR/		Albertson <i>et al.</i> , "Growth and Survival of <i>Helicobacter Pylori</i> in Defined Medium and Susceptibility to Brij 78", <i>Journal of Clinical Microbiology</i> , vol. 36, 1998, pp. 1232-1235, XP002238062	
		Bauer <i>et al.</i> , "Improved Expression of Human Interleukin-2 in High-Cell-Density-Density Fermenter Cultures of <i>Escherichia Coli</i> K-12 by a Phosphotransacetylase Mutant", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 1296-1302	
		Bonsignore <i>et al.</i> , "Development of a Chemically Defined Medium for Bacterial Biotin Production", 1989, <i>Abstr. Pap. Am. Chem. Soc.</i> 198 Meet, MBTD 199	
		Box & Wilson, "On the Experimental Attainment of Optimum Conditions", 1951, <i>J. Roy. Statist. Soc.</i> , B13: 1-45	
		Chalmers <i>et al.</i> , "Effects of Temperature on <i>Escherichia Coli</i> Overproducing $\beta$ -Lactamase or Human Epidermal Growth Factor", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 104-111	
		Evans, D.J. <i>et al.</i> , "Identification of Four New Prokaryotic Bacterioferritins, from <i>Helicobacter Pylori</i> , <i>Anabaena Variabilis</i> , <i>Bacillus Subtilis</i> and <i>Treponema Pallidum</i> , by Analysis of Gene Sequences", 1995, <i>Gene</i> , 153: 123-127	
		De Vuyst, L., "Nutritional Factors Affecting Nisin Production by <i>Lactococcus Lactis</i> Subsp. <i>Lactis</i> NIZO 22186 in a Synthetic Medium", 1995, <i>J. Appl. Bacteriol.</i> , 78: 28-33	
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		Konstantinov <i>et al.</i> , "Physiologically Motivated Strategies for Control of the Fed-Batch Cultivation of Recombinant <i>Escherichia Coli</i> for Phenylalanine Production", 1991, <i>J. Ferm. Bioeng.</i> , 71: 350-355	
		Kopetzki <i>et al.</i> , "Control of Formation of Active Soluble or Inactive Insoluble Baker's Yeast $\alpha$ -Glucosidase PI in <i>Escherichia Coli</i> by Induction and Growth Conditions", 1989, <i>Mol. Gen. Genet.</i> , 216: 149-155	
↓		Lee & Lee, "Enhanced Production of Poly(3-hydroxybutyrate) by Filamentation-Suppressed Recombinant <i>Escherichia Coli</i> in a Defined Medium", 1996, <i>Journal of Environmental Polymer Degradation</i> , 4(2): 131-134	

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/AR/		Luli & Strohl, "Comparison of Growth, Acetate Production, and Acetate Inhibition of <i>Escherichia Coli</i> Strains in Batch and Fed-Batch Fermentations", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 640-645	
		MacDonald & Neway, "Effects of Medium Quality on the Expression of Human Interleukin-2 at High Cell Density in Fermentor Cultures of <i>Escherichia Coli</i> K-12", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 640-645	
		Manetti, R. et al., "Helicobacter Pylori Cytotoxin: Importance of Native Conformation for Induction of Neutralizing Antibodies", 1995, <i>Infect. Immun.</i> , 63: 4476-4480	
		Okita et al., "Effect of Induction Temperature on the Production of Malaria Antigens in Recombinant <i>E. Coli</i> ", 1989, <i>Biotechnol. Bioeng.</i> , 34: 854-862	
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		Rappuoli et al., "Development of a Vaccine Against <i>Helicobacter Pylori</i> : A Short Overview", 1993, <i>European Journal of Gastroenterology and Hepatology of Helicobacter Pylori Infection</i> , Proceedings of an Interdisciplinary Meeting (Geneva, June 18-19, 1993) J.J. Misiewicz, Ed. (CS Current Science) pp. S76-S78	
		Rappuoli, R., "Toxin Inactivation and antigen Stabilization: Two Different Uses of Formaldehyde", 1994, <i>Vaccine</i> , 12(7): 579-581	
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		Stephennne, J., "Development and Production Aspects of a Recombinant Yeast-Derived Hepatitis B Vaccine", 1990, <i>Vaccine</i> , 8: S69-S73	

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09/30/2008 /AR/09/30/2008		Stratakalis <i>et al.</i> , "Development of an Escherichia Coli Culture and Fermentation Process for P <sub>1</sub> -Regulated Expression of HIV-1 Protease," 1991, <i>Abstr. Gen. Meet. Am. Soc. Microbiol.</i> , 91 Meet, 190	
/AR/		Zhang <i>et al.</i> , "Process Characterization Studies to Facilitate Validation of a Recombinant Protein Fermentation," 1998, in: Kelley & Ramelmeier (eds) <i>ACS Symposium Ser 698</i> : 12-27	
/AR/		Zhang & Greasham, "Chemically Defined Media for Commercial Fermentations," 1999, <i>Appl. Microbiol. Biotechnol.</i> , 51:407-421	
/AR/		Moser, A. (1985) Chapters 14-16 of <i>Fundamentals of Biochemical Engineering</i> (ed. Brauer)	
/AR/		Carr <i>et al.</i> , <i>Circulatory Shock</i> , 44(3): 126-37 (1994)	
		International Search Report in Counterpart International Application PCT/US04/00234	

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